UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA v. EV3, INC., Defendant.	Criminal No. 1:18-cr-10461-JGD

EV3, INC'S SENTENCING MEMORANDUM

Defendant ev3, Inc. submits this memorandum in support of the parties' sentencing recommendation set forth in the Plea Agreement, dated and filed December 7, 2018 (ECF No. 8).[1]

The Plea Agreement now before the Court for approval was entered into pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C). This resolution is the culmination of a multi-year investigation by the Department of Justice and the United States Attorney's Office for the District of Massachusetts that commenced in 2011. Over time, this matter involved dozens of witness interviews and grand jury testimony, more than two dozen substantive presentations, and extensive settlement negotiations, including experts retained for purposes of damages analysis. ev3 and DOJ eventually negotiated an agreement that calls for the imposition of significant financial penalties, including a fine of $11,900,000 and forfeiture of $6,000,000, as well as compliance terms reflected in a Side Letter between Medtronic plc—which acquired ev3, via its 2015 acquisition of Covidien plc, more than five years after the conduct at issue—and DOJ, providing for certain compliance measures and government oversight through mid-2021. *See* Side Letter, ECF No. 8 (Ex. B).

Under the terms of Rule 11(c)(1)(C), this Court is authorized to either accept or reject the sentence recommended in the Plea Agreement. For the reasons stated herein, ev3 submits that the proposed sentence is fair and just under all the circumstances. In addition to its punitive aspects and remedial measures, the recommended sentence recognizes that ev3 provided substantial cooperation to the Government, that the misconduct at issue occurred long before (and two companies before) Medtronic's acquisition of ev3, and that there are no allegations of patient harm. The lengthy substantive negotiations have ensured that neither party has hastily entered into these agreements; rather, they are the product of an extensive, substantive, good faith, and adversarial process.

The Plea Agreement fully satisfies the objectives of criminal sentencing set forth in 18 U.S.C. § 3553(a). Accordingly, ev3 requests that the Court accept ev3's plea and impose the sentence jointly recommended in the Plea Agreement.

FACTUAL BACKGROUND

A. ev3, Onyx, and the Conduct at Issue

Pursuant to the Plea Agreement, ev3 will plead guilty to a single misdemeanor violation of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 331(a), 333(a)(1). The Government alleges that between August 2005 and December 2009 ev3 introduced into interstate commerce the medical device known as the Onyx Liquid Embolic System without a required premarket approval ("PMA") for intended uses outside the brain. *See* Information ¶¶ 26-27, ECF No. 8 (Ex. A); Plea Agreement ¶ 1.

By way of background, in July 2005, the U.S. Food and Drug Administration granted a PMA for Onyx, a liquid embolic agent that solidifies upon contact with blood, for pre-surgical

[1] The Plea Agreement and its exhibits, including the Side Letter and Information, are attached hereto as Appendix A.

embolization of brain arteriovenous malformations ("BAVMs"). Information ¶ 10. BAVMs are essentially tangles of abnormal or malformed blood vessels in the brain that, left untreated, can cause bleeding in the brain, seizures, stroke, or other serious neurological problems. Information ¶ 10. Onyx greatly expanded physicians' treatment options for this rare condition. In treating BAVMs with Onyx, neurointerventional radiologists or neurosurgeons use catheter access to inject Onyx into the malformed blood vessels, which stops the flow of blood to the BAVM and allows a surgeon to remove the vessel entanglement surgically. Information ¶ 11.

Onyx was initially developed by Micro Therapeutics, Inc. ("MTI"). MTI applied to the FDA for a PMA to distribute Onyx in the United States for the pre-surgical embolization of BAVMs. In November 2005, ev3—a Minnesota-based corporation that manufactured medical devices used to treat vascular diseases—acquired MTI, which became the neurovascular division of ev3. Information ¶ 1.

Shortly after PMA approval in 2005, the Government alleges that ev3 began marketing Onyx to physicians for uses that were not approved by the FDA. Information ¶ 14. For example, the Information alleges that Onyx was sold to vascular surgeons and interventional radiologists who used Onyx for peripheral malformations—*i.e.*, surgical procedures outside the brain. Information ¶ 15. The Government also contends that ev3 "compensated territory managers for sales of Onyx for unapproved uses." Information ¶ 16.

While ev3 takes full responsibility for marketing Onyx for peripheral uses in certain instances, it is important to note that Onyx had been approved for peripheral use for years in more than 70 countries. There was considerable medical literature discussing the benefits of using Onyx for peripheral lesions, and this topic was widely discussed at international medical conferences attended by U.S. physicians. Significantly, the Information does not allege harm to

any patients as a result of the use of Onyx in peripheral procedures. Indeed, Onyx has undisputed therapeutic benefits for patients, and has had an exemplary safety profile since it was first launched internationally in 1999. Moreover, the Government does not allege that ev3 made any false or misleading statements in its marketing of Onyx.

B. Corporate Acquisitions

In July 2010—after the misconduct alleged in the Information ended—Covidien purchased ev3, and the Irvine-based neurovascular business became known as Covidien Neurovascular.[2] Side Letter at 1. Five years later, in January 2015, Medtronic acquired Covidien. Side Letter at 1. The Onyx revenue was a very small fraction of the overall Covidien revenues at the time of the acquisition and represents an even smaller portion of Medtronic's.

The alleged misconduct occurred between August 2005 and December 2009—ending five years before Medtronic acquired Covidien in January 2015, and several months before Covidien acquired ev3 in July 2010. Indeed, the Plea Agreement specifically states that Medtronic "acquired ev3 several years after the criminal conduct that resulted in th[e] [P]lea [A]greement and had no prior knowledge of or involvement in such conduct." Plea Agreement ¶ 5(e); *see also* Press Release, DOJ, Medical Device Maker ev3 to Plead Guilty and Pay $17.9 Million for Distributing Adulterated Device; Covidien Paid $13 Million to Resolve Civil Liability for Second Device (Dec. 4, 2018) ("Medtronic played no role in the criminal conduct . . . .").

C. Government Investigation and Cooperation

ev3 has provided substantial cooperation over the course of DOJ's investigation. DOJ first issued a subpoena to ev3 calling for production of documents on May 7, 2011. Less than

[2] Covidien Neurovascular was not a distinct corporate entity from Covidien.

two weeks later, ev3's counsel met with DOJ to discuss its priorities for documents and custodians, and started document production by June 2011. Over the next few years, ev3 participated in more than thirty weekly calls and meetings with DOJ to discuss document production. DOJ made at least sixteen specific requests—*e.g.*, to prioritize the production of certain documents or particular witnesses' files—with which ev3 always complied on DOJ's timeframe. ev3 provided a weekly chart describing the status of the document production and a list of custodians.[3] In total, ev3 made over fifty separate productions to DOJ, producing approximately five million pages of responsive material. ev3 further assisted DOJ by facilitating interviews and grand jury appearances for over twenty-five then-current and former employees. Over the course of approximately two dozen substantive meetings, ev3 also shared the results of its extensive internal investigation, addressing all the issues of concern or interest to DOJ.

Finally, ev3 accommodated DOJ's requests to extend the timeline of the investigation, executing numerous tolling agreements. Four federal prosecutors working on this matter left the Government during the course of investigation, causing delays during each transition. Other delays in this matter were attributable to ev3, such as when Medtronic assumed responsibility for this matter, but at no time did DOJ determine that any of the entities (ev3, Covidien, or Medtronic) were uncooperative.

D. The Plea Agreement and Side Letter

After extensive substantive settlement negotiations over the course of many months, ev3 entered into a Plea Agreement with DOJ on December 7, 2018, to accept responsibility for its misconduct. Plea Agreement ¶ 1. The Plea Agreement calls for a total monetary sanction of $17.9 million. Plea Agreement ¶ 5. The parties have also entered into a Side Letter, which

[3] These charts showed ev3's collection, review, and production efforts with respect to the types of data and documents—such as current email, backup email, and paper documents—available for each of the nearly seventy

requires a comprehensive monitoring framework ensuring that the sales and marketing of specified ev3 products remains compliant with the law in the future. Side Letter at 3-7. The Side Letter provides terms for government monitoring of the Medtronic business unit containing Onyx. Side Letter at 3-7. The key terms of the Plea Agreement and the Side Letter are summarized below.

1. *The Plea Agreement*

Under the Plea Agreement, ev3 will plead guilty to a misdemeanor violation of the FDCA, 21 U.S.C. §§ 331(a), 333(a)(1). Plea Agreement ¶ 1. ev3 also agreed to pay a criminal fine in the amount of $11,900,000, forfeiture in the amount of $6,000,000, and a mandatory special assessment of $125. Plea Agreement ¶ 5. By entering into the Plea Agreement, ev3 has agreed to admit responsibility "expressly and unequivocally" for the misconduct detailed in the Information. Plea Agreement ¶ 1.

The aforementioned financial penalties were negotiated by the parties and were based on numerous factors, all driven by the Guidelines' principle that the first step is identifying ev3's pecuniary gain from its off-label marketing practices. The parties first ascertained the volume of off-label sales of Onyx for the relevant time period, assessed and debated the extent to which a physician's decision to use Onyx off-label was caused by ev3's conduct, and then adjusted for the cost of the goods sold. The parties then negotiated over other adjustments including the relevant time period, First Amendment considerations pertaining to restrictions on commercial speech, and litigation risk. ev3 and its consultants also developed a model to assess the pecuniary gain from the offense and the parties had roughly ten negotiating sessions—using this model—just on the size of the fine and forfeiture.

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custodians DOJ requested.

The Plea Agreement provides for no restitution, recognizing that because "there are no . . . known victims" of the conduct at issue, "the complication and prolongation of the sentencing process that would result from an attempt to fashion a proper restitution order . . . outweighs the need to provide restitution." Plea Agreement ¶ 5(d).

The Plea Agreement also provides that ev3 will not be placed on probation because Medtronic "(1) acquired ev3 several years after the criminal conduct that resulted in th[e] [P]lea [A]greement and had no prior knowledge of or involvement in such conduct; (2) took significant steps to prevent any future conduct of the kind that resulted in this [P]lea [A]greement; (3) committed to certain compliance provisions related to the medical devices at issue in this case; and (4) agreed to make the results of certain compliance assessments available to the United States," pursuant to the Side Letter. Plea Agreement ¶ 5(e).

The sentence presented to this Court for approval is submitted under Federal Rule of Criminal Procedure 11(c)(1)(C). Under Rule 11(c)(1)(C), "the plea agreement may specify that an attorney for the government will . . . agree that a specific sentence or sentencing range is the appropriate disposition of the case." Fed. R. Crim. P. 11(c)(1)(C). This Court is then obligated to either accept or reject the sentence recommended by the parties. Rule 11(c)(1)(C) pleas are very common in criminal cases involving corporations. Corporate defendants and attorneys for the government often negotiate Rule 11(c)(1)(C) pleas in order to account for the interests of innocent employees, shareholders, and investors, and also to promote efficient and just resolution of matters via plea rather than trial. Not surprisingly, the vast majority of corporate criminal charges involve Rule 11(c)(1)(C) pleas in this district and elsewhere.[4] Indeed, since December 2012, at least 85 companies have entered into Rule 11(c)(1)(C) pleas in federal courts.[5]

[4] In recent years, a number of life sciences companies have pled guilty to criminal conduct pursuant to Rule 11(c)(1)(C) in the District of Massachusetts. *See, e.g.*, Plea Agreement at 2, *United States v. Warner Chilcott Sales*

2. *DOJ Side Letter Agreement*

As part of the resolution of this matter, the parties agreed to enter into a Side Letter Agreement with compliance terms and government monitoring of the relevant business unit, which will be in effect through April 2021. As detailed in the Side Letter, the Government acknowledged that "the conduct that forms the basis of the criminal charge occurred prior to both Medtronic's acquisition of Covidien and prior to Covidien's acquisition of ev3, Inc." Side Letter at 2. Moreover, "Medtronic and Covidien had no prior knowledge of or involvement with any of the conduct that formed the basis of the criminal charge." Side Letter at 2.

The Side Letter also notes that after acquiring Covidien and ev3, and "without prompting or direction from the United States, Medtronic initiated additional compliance measures to prevent potential violations of the FDCA by ev3, Inc. and its employees." Side Letter at 3. The company also developed additional compliance measures to prevent misconduct similar to that outlined in the Information. Side Letter at 3. These measures include maintaining an Ethics and Compliance Program governing all Medtronic operating units. That Compliance Program

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U.S. (LLC), No. 15-cr-10327 (D. Mass. Oct. 29, 2015) (ECF No. 2); Plea Agreement at 3, *United States v. GlaxoSmithKline LLC*, No. 12-cr-10206 (D. Mass. July 2, 2012) (ECF No. 2); Plea Agreement at 6, *United States v. Merck Sharp & Dohme Corp.*, No. 11-cr-10384 (D. Mass. Dec. 12, 2011) (ECF No. 12); Plea Agreement at 3, *United States v. Elan Pharm., Inc.*, No. 10-cr-10431 (D. Mass. Feb. 28, 2011); Revised Plea Agreement at 8, *United States v. SB Pharmco Puerto Rico, Inc.*, No. 10-cr-10355 (D. Mass. Nov. 8, 2010) (ECF No. 10); Plea Agreement at 10, *United States v. Forest Pharm., Inc.*, No. 10-cr-10294 (D. Mass. Sept. 15, 2010) (ECF No. 7); Plea Agreement at 5, *United States v. Ortho-McNeil Pharm., LLC*, No. 10-cr-10147 (D. Mass. Apr. 29, 2010) (ECF No. 3); Plea Agreement at 3, *United States v. Pharmacia & Upjohn Co.*, No. 09-cr-10258 (D. Mass. Sept. 2, 2009) (ECF No. 2); Plea Agreement at 3, *United States v. Biovail Pharm., Inc.*, No. 08-cr-10124 (D. Mass. Sept. 14, 2009); Plea Agreement at 1, *United States v. Bryan Corp.*, No. 07-cr-10353, (D. Mass. Dec. 20, 2007.) (ECF No. 5); Plea Agreement at 3, *United States v. Pharmacia & Upjohn Co., Inc.*, No. 07-cr-10099 (D. Mass. Apr. 3, 2007) (ECF No. 2); Plea Agreement at 3, *United States v. Schering Sales Corp.*, No. 06-cr-10250-RBS (D. Mass. Sept. 20, 2006) (ECF No. 12); Plea Agreement at 5, *United States v. Serono Laboratories, Inc.*, No. 05-cr-10282 (D. Mass. Dec. 21, 2005) (ECF No. 7); Plea Agreement at 2, *United States v. Warner-Lambert Co. LLC*, No. 04-cr-10150-RGS (D. Mass. May 13, 2004) (ECF No. 2); *United States v. Bayer Corp.*, No. 03-cr-10118-RG (D. Mass. May 8, 2003) (ECF No. 7); Plea Agreement at 2, *United States v. TAP Pharm. Products, Inc.*, No. 98-cv-10547 (D. Mass. Oct. 1, 2001) (ECF No. 44).

[5] Rule 11(c)(1)(C) pleas are also used widely in other industries outside of the pharmaceutical and medical device industries. For example, Tyson Poultry recently pled guilty to a Clean Water Act charge through a Rule 11(c)(1)(C) plea in the Western District of Missouri. *See* Plea Agreement 1, *United States v. Tyson Poultry, Inc.*, No. 3:17-cr-05041 (W.D. Mo. Sept. 27, 2017) (ECF No. 8).

includes governance oversight by an Audit Committee of the Board of Directors, which is responsible for overseeing compliance with all applicable laws and regulations, including the FDCA. The Audit Committee reports to the Board of Directors, and receives regular reports from Medtronic's Global Chief Ethics and Compliance Officer regarding the results of audits, significant investigations, and any corrective or preventative actions. Side Letter at 4-5.

In the Side Letter, the company agreed to five "Cooperation Commitments." First, it will promptly inform employees of its Neurovascular business unit of ev3's guilty plea. Side Letter at 3-4. Second, it will maintain its existing Compliance Program. Side Letter at 4-5. Third, it will design employee compensation to ensure that variable pay, bonuses, and quotas for its Neurovascular sales force only incentivize the marketing of the Onyx device for indications approved by the FDA. Side Letter at 5. Fourth, it will develop a policy for the Neurovascular business unit that governs the appropriate role of sales personnel in providing technical assistance to physicians regarding uses of devices that have not been approved by the FDA. Side Letter at 5. Finally, it will conduct annual compliance reviews of the Neurovascular business unit's marketing and sales practices for Onyx, as well as two other legacy ev3 devices, for three review periods lasting through 2021. Side Letter at 6. This Annual Review will include a summary of findings and areas of improvement, an analysis of certain communications,[6] and relevant corrective actions. These materials will be provided to the Audit Committee and, upon request, the Government. Side Letter at 7. Finally, the company will provide a certification to the

[6] Specifically, the annual review will include "an analysis of a representative sample of documented communications between Medtronic's Neurovascular Business and customers regarding the sale and marketing of the Covered Devices, the approved marketing materials for the Covered Devices, any unapproved marketing materials for the Covered Devices identified by any employee of Medtronic, the sales incentive plans for the Covered Devices, training assessments of sales and marketing personnel in the Neurovascular Division, and a review of any potential compliance violations involving the Covered Devices identified by any employee of Medtronic or reviewed by Medtronic's Legal or Compliance Department if identified by an outside source." Side Letter at 6-7.

Government after each annual review period. Side Letter at 7. Failure to abide by the requirements to maintain the Compliance Program or to provide the annual certifications or other Annual Review materials to the Government will result in a penalty of $20,000 per day. Side Letter at 8.

ARGUMENT

A. THE PROPOSED SENTENCE SERVES THE PURPOSES OF SENTENCING SET FORTH IN 18 U.S.C. § 3553(A).

Criminal sentencing proceedings are guided by the factors set forth in 18 U.S.C. § 3553(a). The overarching principle of sentencing is that the punishment imposed must be "sufficient, but not greater than necessary" to comply with the purposes of the statute. *Id.* This principle "necessarily informs a sentencing court's consideration of the entire constellation of [S]ection 3553(a) factors," and a court should "strive to construct a sentence that is minimally sufficient to achieve the broad goals of sentencing." *United States v. Rodríguez*, 527 F.3d 221, 228 (1st Cir. 2008). In relevant part, Section 3553(a) instructs courts to consider "the nature and circumstances of the offense and the history and characteristics of the defendant," the need for the sentence to reflect the "seriousness of the offense" and "to provide just punishment for the offense," and "any pertinent policy statement," including those issued by the Sentencing Commission.

Here, the sentence set forth in the Plea Agreement is "sufficient, but not greater than necessary, to comply with the purposes set forth in" 18 U.S.C. § 3553(a). The terms of the Plea Agreement reflect the seriousness of the offense committed by ev3 and provide adequate deterrence. 18 U.S.C. § 3553(a)(2)(A)-(B).

In support of the proposed sentence here, ev3 submits that, without minimizing the conduct, the adulteration at issue in this case involved an unapproved use for Onyx that has been approved for years in 74 countries around the world. Moreover, the use of Onyx in peripheral procedures is not associated with an increased risk of adverse events. In assessing whether the substantial monetary sanction in this case is appropriate, those factors are important.

Additionally, the company that markets Onyx today is a fundamentally different entity from the one described in the Information. The misconduct at issue took place from August 2005 through December 2009. ev3 was acquired by Covidien in July 2010—several months after the misconduct ended—and then Covidien was acquired by Medtronic *five years* after the misconduct ended. There is no overlap between the ev3 Board of Directors during the relevant timeframe and the current ev3 Board.

Medtronic also has dedicated extensive resources and effort to compliance, and its robust compliance program now governs the legacy business units of ev3. *See* 18 U.S.C. § 3553(a)(2)(C) (instructing Courts to consider whether the public is protected "from further crimes of the defendant"). First, pursuant to the company's charter, Medtronic's Audit Committee is vested with oversight over its worldwide compliance program. The Audit Committee receives quarterly reports from the Global Chief Ethics and Compliance Officer concerning the performance of the company's global compliance program, including the results of significant compliance audits and investigations and any resulting corrective or preventative actions. The company also has an Executive Compliance Committee, which meets in person quarterly to provide oversight, monitor effectiveness, discuss risks, set strategic direction, and ensure that there are adequate compliance resources. Finally, Medtronic's Chief Human Resources Officer, Chief Financial Officer, General

Counsel, and Chief Global Ethics & Compliance Officer approve discipline for any significant misconduct worldwide.

II. THE PUNISHMENT IS APPROPRIATE UNDER THE SENTENCING GUIDELINES.

While the fine provisions of the Sentencing Guidelines do not apply to organizational defendants for misdemeanor violations of the FDCA, the proposed fine is entirely consistent with the guidelines. *See* USSG § 8C2.1; *see also* 18 U.S.C. § 3553(a)(2)(B) (instructing Courts to consider whether the proposed sentence "afford[s] adequate deterrence to criminal conduct"). Specifically, the parties agree that the base fine—or the reasonably estimated pecuniary gain from the conduct at issue—is $6,000,000 under USSG § 8C2.4(a)(2), and pursuant to USSG § 8C2.5, the culpability score is seven. The culpability score was derived by (1) adding three points to the base score of five, because ev3 had more than 200 employees and a high-level individual "participated in, condoned, or was willfully ignorant of the offenses," USSG § 8C2.5(b)(3)(A); and (2) subtracting one point because ev3 recognized and affirmatively accepted responsibility for its criminal conduct. *See* USSG § 8C2.5(g)(3). Pursuant to USSG § 8C2.6, the multiplier is 1.4 to 2.8, which results in a Guideline range of $8,400,000 to $16,800,000. Plea Agreement ¶ 4. However, under 18 U.S.C. § 3571(d), "the defendant may be fined not more than the greater of twice the gross gain or twice the gross loss," which here is $6,000,000. *See also* Plea Agreement ¶ 2. The parties thus agreed that ev3 would pay a criminal fine of $11,900,000 and forfeiture in the amount of $6,000,000, both to be paid within seven days of the date of sentencing. Plea Agreement ¶ 5(a), (c). Thus, after years of extensive negotiations—and upon consideration of all of the factors set forth in 18 U.S.C. §§ 3553(a) and 3572—the parties have agreed that the fine is within the guidelines and will result in an appropriate sentence.

The Sentencing Guidelines also provide that cooperation is "timely" if it begins "essentially at the same time as the organization is officially notified of a criminal investigation." § 8C2.5 cmt. 13 (U.S. Sentencing Comm'n 2018). As previously described, ev3 provided the Government with substantial cooperation over the course of DOJ's investigation, including producing more than five million pages of documents, making current and former employees available for interviews and grand jury appearances, and sharing the results of an extensive internal investigation with DOJ over the course of approximately two dozen substantive meetings.

* * *

The misconduct at issue ended almost a decade ago, and occurred under the purview of a company that has since been twice acquired. As described in more detail in ev3's Motion to Waive the Presentence Report and Consolidate the Plea and Sentencing Hearings, also filed on January 18, 2019, the interests of justice would be served by imposing the punishment and remedial measures set forth in the Plea Agreement and bringing this matter to a conclusion after these many years. ev3 thus respectfully requests that this Court accept its Rule 11(c)(1)(C) guilty plea and impose the sentence recommended in the Plea Agreement.

Dated: January 18, 2019

Respectfully submitted,

Boston, Massachusetts

/s/ Joshua S. Levy

Joshua S. Levy (BBO # 563017)
Kirsten B. Liedl (BBO # 687889)
ROPES & GRAY LLP
Prudential Tower
800 Boylston Street
Boston, Massachusetts 02199-3600
joshua.levy@ropesgray.com
kirsten.liedl@ropesgray.com

Telephone: (617) 951-7000
Facsimile: (617) 951-7050

Attorneys for Defendant,
ev3, Inc.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

Dated: January 18, 2019

/s/ *Joshua S. Levy*
Joshua S. Levy